

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., and)
BAYER HEALTHCARE LLC,)
Plaintiffs,)
v.) C.A. No. 05-349-GMS
BAXTER INTERNATIONAL INC., and) Jury Trial Demanded
BAXTER HEALTHCARE CORPORATION,)
Defendants.) REDACTED VERSION DI 287
)

BAXTER HEALTHCARE CORPORATION,)
Counterclaimant,)
v.)
TALECRIS BIOTHERAPEUTICS, INC., and)
BAYER HEALTHCARE LLC,)
Counterdefendants.)

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO BAXTER'S MOTION
*IN LIMINE NO. 3 TO BAR DR. RAVETCH FROM TESTIFYING REGARDING
INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS***

Bradford J. Badke, Esquire
Gabrielle Ciuffreda, Esquire
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 10036
Of Counsel for Counterclaim Defendant
Bayer Healthcare LLC

Redacted Version Filed: May 10, 2007
Date: May 7, 2007

Jeffrey B. Bove (#998)
Mary W. Bourke (#2356)
Mark E. Freeman (#4257)
Jaclyn M. Mason (#4737)
Dana K. Hammond (#4869)
Christopher E. Jeffers (*pro hac vice*)
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899-2207
(302) 658-9141
*Attorneys for Plaintiffs and
Counterclaim Defendants*

INTRODUCTION

Plaintiffs Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC (“Plaintiffs”) hereby oppose the motion *in limine* filed by Defendants Baxter International Inc. and Baxter Healthcare Corporation (“Baxter”) to prohibit Plaintiffs’ expert, Dr. Jeffrey V. Ravetch from providing any evidence or argument regarding the Doctrine of Equivalents as applied to claims 10, 12, 15-18 (Docket Item [“D.I.”] 249). Contrary to Baxter’s assertion that Dr. Ravetch’s opinions are “based merely on speculation,” Dr. Ravetch’s opinions are based upon two sets of data from Baxter’s manufacturing facility in Lessines, Belgium. Dr. Ravetch clearly stated the basis for his opinion that Baxter’s manufacturing process infringes the claims of the ‘191 patent, either literally, or under the doctrine of equivalents.¹ For these reasons, Baxter’s Motion should be denied.

ARGUMENT

Analysis of infringement under the doctrine of equivalents “focuses on whether the element in the accused device ‘performs substantially the same function in substantially the same way to obtain the same result’ as the claim limitation.” *Aquatex Industries, Inc. v. Techniche Solutions*, 419 F.3d 1374 (Fed. Cir. 2005), *citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). The claims of the ‘191 patent are directed to processes and conditions that result in the lowering of anticomplement activity (“ACA”) in an IgIV solution. The data in the ‘191 patent clearly demonstrate such a decrease in ACA. (Mason Dec.², Ex. 4, Tables 3, 5 and 7). Infringement of the ‘191 patent under the doctrine of equivalents turns on

¹ Plaintiffs reserve the right to argue that other claim elements are infringed under the doctrine of equivalents if the claim construction is altered on appeal.

² The “Mason Dec.” is the Declaration of Jaclyn M. Mason in Support of Plaintiffs’ Oppositions to Baxter’s Motions *in Limine* Nos. 1-5, filed concurrently herewith.

whether the conditions of Baxter's accused process are sufficiently similar to the claimed process to function in the same way to achieve a lowering of ACA. In forming his opinion on infringement under the doctrine of equivalents Dr. Ravetch relied on two sets of data that demonstrate just such a decrease in ACA.

1. Claim 10 – Ionic Strength

Claim 10 of the '191 patent states, "The method of claim 1, wherein the ionic strength is less than about 0.001 M." (*Id.*)

REDACTED

. (*Id.*, Ex. 5, ¶ 79.)

REDACTED

(*Id.*, Ex. 6.)

(*Id.*, Ex. 5, ¶ 79.)

REDACTED

(*Id.*, Ex. 5, ¶ 78

(*Id.*, Ex. 7.)

REDACTED

(*Id.*, Exs. 8, 9

REDACTED

REDACTED

(*Id.*, Exs. 10-12.) These data formed the basis of Dr. Ravetch's opinion

REDACTED

Baxter's assertion that Dr.

Ravetch's opinion is not based on data is wrong. Dr. Ravetch's opinion is based on two separate sets of data, one obtained by Plaintiffs and one obtained by Baxter.

Baxter also had ample opportunity to depose Dr. Ravetch about his opinions during his two-day deposition. Baxter failed to avail themselves of this opportunity. A search of the transcript of Dr. Ravetch's deposition does not yield a single mention of the phrase "ionic strength". Baxter should not now be allowed to plead "ignorance" of Dr. Ravetch's opinions in a transparent attempt to exclude damaging testimony.

2. Claims 12 and 15-18 - Tonicity

Baxter's criticism of Dr. Ravetch's opinions regarding tonicity are equally devoid of merit. Claims 12 and 15-18 contain limitations regarding the tonicity of the claimed solution. Dr. Ravetch opined that Baxter's manufacturing process infringed these claims either literally under the doctrine of equivalents. (*Id.*, Ex. 5.)

The osmolarity of the Baxter product is printed on their package insert. (*Id.*, Ex. 13.) Dr. Ravetch opined that tonicity and osmolarity are equivalent in biological systems. (*Id.*, Ex. 5 at ¶¶ 83, 89.) As such, the disclosed osmolarity of the solutions fall within the stated ranges of the '191 patent, and therefore infringe.

Baxter's assertion that Dr. Ravetch needs to experimentally determine the tonicity of Baxter's product is baseless

REDACTED

(*Id.*, Ex. 5 at ¶¶ 82, 88 and 93.)

REDACTED

(*Id.*, Exs. 8, 9, 11, 12.)

The osmolality of the solution is sufficiently similar to the claimed range to function in the same way to achieve the same result (lowering of ACA).

CONCLUSIONS

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Baxter's motion *in limine* No. 3. The jury should be permitted to hear Dr. Ravetch's opinions and testimony regarding infringement under the doctrine of equivalents. A proposed form of Order is attached hereto as Exhibit A.

Redacted Version Filed: May 10, 2007

Date: May 7, 2007

Respectfully submitted,

Bradford J. Badke, Esquire
Gabrielle Ciuffreda, Esquire
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 10036
Of Counsel for Counterclaim Defendant
Bayer Healthcare LLC

DC48039

/s/ Jeffrey B. Bove
Jeffrey B. Bove (#998)
Mary W. Bourke (#2356)
Mark E. Freeman (#4257)
Jaclyn M. Mason (#4737)
Dana K. Hammond (#4869)
Christopher E. Jeffers (*pro hac vice*)
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street, P.O. Box 2207
Wilmington, DE 19899-2207
(302) 658-9141
Attorneys for Plaintiffs and
Counterclaim Defendants

CERTIFICATE OF SERVICE

I hereby certify on this 7th day of May, 2007 I electronically filed the foregoing **Plaintiffs' Opposition to Baxter's Motion *In Limine* No. 3 to Bar Dr. Ravetch From Testifying Regarding Infringement Under the Doctrine of Equivalents** with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

Philip A. Rovner, Esquire Potter Anderson & Corroon LLP Hercules Plaza P. O. Box 951 Wilmington, DE 19899 (302) 984-6140 provner@potteranderson.com	Susan Spaeth, Esquire Townsend and Townsend and Crew LLP 379 Lytton Avenue Palo Alto, CA 94301-1431 (415) 576-0200 smSPAETH@townsend.com
---	--

I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on May 7, 2007.

<u>Via Hand Delivery and E-Mail</u>	<u>Via Federal Express and E-Mail</u>
Philip A. Rovner, Esquire Potter Anderson & Corroon LLP Hercules Plaza P. O. Box 951 Wilmington, DE 19899 (302) 984-6140 provner@potteranderson.com	Susan Spaeth, Esquire Townsend and Townsend and Crew LLP 379 Lytton Avenue Palo Alto, CA 94301-1431 (415) 576-0200 smSPAETH@townsend.com

/s/ Jeffrey B. Bove

Jeffrey B. Bove (#998)
CONNOLLY BOVE LODGE & HUTZ LLP
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801
Telephone: (302) 658-9141
jbove@cblh.com
Attorneys for Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC

Bradford J. Badke
Gabrielle Ciuffreda
ROPES & GRAY LLP
1251 Avenue of the Americas
New York, NY 10020-1105
(212) 596-9000
Attorneys for Bayer Healthcare LLC